

Rule 2. Registration of Radiation Machine Facilities and Services

410 IAC 5-2-1 Scope of rules; registration of materials

Sec. 1. (a) 410 IAC 5-2 provides for the registration of radiation machine facilities.

(b) In addition to the requirements of 410 IAC 5-2, all registrants are subject to the applicable provisions of other sections of 410 IAC 5.

(c) In addition to 410 IAC 5-2-1(a) and 410 IAC 5-2-1(b) each person who receives, possesses, uses, transfers or acquires radioactive material shall register such materials with the board in accordance with the requirements of 410 IAC 5-2. This requirement is effective until the state enters into an effective agreement with the U.S. Nuclear Regulatory Commission for the transfer of regulatory authority under Sec. 274(b) of the Atomic Energy Act of 1954, as amended (73 Stat. 689) at which time 410 IAC 5-3, Licensing of Radioactive Material, becomes effective.

410 IAC 5-2-2 Definitions

Sec. 2. (a) For purposes of 410 IAC 5-2, "facility" means the location at which one or more devices or sources are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.

(b) Pursuant to 410 IAC 5-2-1(c) "radiation machine" as used throughout 410 IAC 5-2 also refers to radioactive material.

410 IAC 5-2-3 Exemptions

Sec. 3. (a) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of 410 IAC 5-2, providing dose equivalent rate averaged over an area of 10 square cm does not exceed 0.5 mrem per hour at 5 cm from any accessible surface of such equipment. The production, testing or factory servicing of such equipment shall not be exempt.

(b) Radiation machines while in transit or storage incident thereto are exempt from the requirements of 410 IAC 5-2.

(c) Domestic television receivers are exempt from the requirements of 410 IAC 5-2.

410 IAC 5-2-4 Application for registration of facility

Sec. 4. Each person having a radiation machine facility shall:

(a) Register such facility with the board prior to the operation of a radiation machine facility. The registration shall be completed on forms furnished by the board and shall contain all the information required by the form and accompanying instructions.

(b) Designate on the application form an individual to be responsible for radiation protection.

410 IAC 5-2-5 Issuance of registration

Sec. 5. (a) Upon a determination that an applicant meets the requirements of 410 IAC 5, the board shall issue a registration.

(b) The board may incorporate in the registration at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation machines as it deems appropriate or necessary.

410 IAC 5-2-6 Notice of changes

Sec. 6. The registrant shall notify the board in writing before making any change which would render the information contained in the registration no longer accurate.

410 IAC 5-2-7 Advertising prohibitions

Sec. 7. No person, in any advertisement, shall refer to the fact that he or his facility is registered with the board pursuant to the provisions of 410 IAC 5-2 and no person shall state or imply that any activity under such registration has been approved by the board.

410 IAC 5-2-8 Dealers and assemblers; duties; notice and reports to board

Sec. 8. (a) Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in this state shall notify the board within 15 days of:

(1) the name and address of persons who have received these machines;

(2) the manufacturer, model, and serial number of each radiation machine transferred; and

(3) the date of transfer of each radiation machine.

(b) In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report prepared in

compliance with requirements of the Federal Diagnostic X-Ray Standard (21 CFR 1020.30(d)) shall be submitted to the board within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

(c) No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used shall meet the requirements of 410 IAC 5.

410 IAC 5-2-9 Bringing radiation machine into state; application

Sec. 9. (a) Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring such machine into the state shall give written notice to the board at least two (2) working days before such machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use; the exact location(s) where the radiation machine is to be used; and states in which this machine is registered. If for a specific case the two working-day period would impose an undue hardship on the person, he may, upon application to the board, obtain permission to proceed sooner.

(b) The person referred to in 410 IAC 5-2-9(a) shall:

- (1) comply with all applicable requirements of the board including the certification of x-ray machine operators;
- (2) supply the board with such other information as the board may reasonably request; and
- (3) not operate within the state on a temporary basis in excess of 180 calendar days per year.